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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,711	06/30/2000	Guy Serre	045636-5037	8393
9629	7590	06/14/2004	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			COOK, LISA V	
			ART UNIT	PAPER NUMBER
			1641	
			DATE MAILED: 06/14/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,711

Applicant(s)

SERRE ET AL.

Examiner

Lisa V. Cook

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3,5-7 and 9-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Amendment Entry

1. Applicants response to the non-Final Office Action mailed 2 January 2003 is acknowledged. In amendment-E filed therein Claims 1, 5-7, 9-10, and 12-15 were modified.

Telephonic Interview

2. Examiner phone attorney Sally Teng (34,297) regarding claim modification for allowance. Specifically Examiner directed Applicant to wording the claims to read on "consisting of" for allowance. Applicant declined the modification. Accordingly the following action was prepared.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3, 5, 7, and 9-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for sequences consisting of sequences 7, 8, and 9, it does not reasonably provide enablement for any and all peptide constructs comprising the three amino acid motif Ser-Cit-His, wherein said motif is an epitope recognized by an auto-antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to utilize the invention commensurate in scope with these claims.

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The instant invention is directed to an isolated peptide comprising the motif Ser-Cit-His. Therefore the claims read on any and all polypeptides, which would include Ser-Cit-His for antibody binding. In other words, the claimed invention reads on any and all peptides comprising Ser-Cit-His irrespective of the amino acids flanking the motif. The prior art teaches that the residues flanking the amino acid motif regulate antibody recognition or binding. The flanking residues may impose conformational constraints upon the presentation of the epitope for antibody binding. Further variability maybe seen when the motifs are repeated or housed in larger sequences. This is supported by the reference of Briggs et al. (European Journal of Cancer, 1993, Vol.29A, No.2, Pages 230-237).

Only sequence identification numbers 7, 8, and 9 are exemplified in autoantibody binding or recognition. Accordingly the specification is not enabled for any and all peptides comprising Ser-Cit-His allowing for antibody binding and/or recognition.

The disclosure does not support claims directed to all possible peptide constructs, which would read on the instant claims, or specifically comprising the motif Ser-Cit-His. Accordingly the claims are not commensurate in scope with any and all peptide molecules comprising Ser-Cit-His as recited in claims 1, 3, 5, 7, and 9-15.

The language of claims 1, 3, 5, 7, and 9-15 are directed to peptides comprising the motif Ser-Cit-His however only sequence identification numbers 7, 8, and 9 are demonstrated in the instant application.

Thomas E. Creighton, in his book, "Proteins: Structures and Molecular Properties, 1984, (pages 314-315) teaches that variation of the primary structure of a protein can result in an instable molecule. He also teaches a single amino acid change can cause a mutant.

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With the exception of SEQ ID NO:7, 8, and 9, the skilled artisan cannot envision the detailed structure of the encompassed compositions and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

There is no guidance in the specification as to how to determine which sequences including the Ser-Cit-His motif other than sequences 7, 8, or 9; would allow for autoantibody binding or recognition. It appears that undue experimentation would be required of one skilled in the art to practice the instant claimed invention using the teachings of the specification. See Ex parte Forman, 230 USPQ 546 BPAI, 1986.

In absence of guidance and/or working examples, one skilled in the art would reasonably conclude that a large number of peptide constricts comprising the Ser-Cit-His would be considered in order to practice the invention. The scope of the claims must bear a reasonable correlation with the scope of enablement. One skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

Response to Arguments

4. Applicants have submitted a new sequence disk containing sequence identification numbers 7, 8, and 9. Prior art of record has been withdrawn, because the references did not teach serine and histidine flanking an arginine which is converted to citrulline. However, the claims have been rejected under 35 USC 112, 1st paragraph.

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5. For reasons aforementioned, no claims are allowed.

6. New ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE NON-FINAL.**

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.



Lisa V. Cook
Patent Examiner
Ramson 3C - 59
Art Unit 1641
3/24/04



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

03/04/04